



## General

### Guideline Title

Lower urinary tract symptoms in men: assessment and management.

### Bibliographic Source(s)

National Clinical Guideline Centre for Acute and Chronic Conditions. Lower urinary tract symptoms in men: assessment and management. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Jun. 38 p. (Clinical guideline; no. 97).

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Clinical Guideline Centre for Acute and Chronic Conditions. Lower urinary tract symptoms. The management of lower urinary tract symptoms in men. London (UK): National Institute for Health and Clinical Excellence (NICE); 2010 May. 34 p. (Clinical guideline; no. 97)

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Recommendations

### Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) for Acute and Chronic Care on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

The following guidance is based on the best available evidence. The full guideline gives details of the methods and the evidence used to develop the guidance. The guideline addendum (see the "Availability of Companion Documents" field) gives details of the methods and the evidence used to develop the 2015 recommendations.

In this guidance, 'mild' refers to an International Prostate Symptom Score (IPSS) of 0 to 7, 'moderate' refers to an IPSS of 8 to 19 and 'severe' refers to an IPSS of 20 to 35.

Recommendations are marked as [new 2015] or [2010]:

- [new 2015] indicates that the evidence has been reviewed and the recommendation has been added or updated.
- [2010] indicates that the evidence has not been reviewed since 2010.

The wording used in the recommendations in this guideline (for example words such as 'offer' and 'consider') denotes the certainty with which the

recommendation is made (the strength of the recommendation) and is defined at the end of the "Major Recommendations" field.

### Initial Assessment

Initial assessment refers to assessment carried out in any setting by a healthcare professional without specific training in managing lower urinary tract symptoms (LUTS) in men.

At initial assessment, offer men with LUTS an assessment of their general medical history to identify possible causes of LUTS, and associated comorbidities. Review current medication, including herbal and over-the-counter medicines, to identify drugs that may be contributing to the problem. [2010]

At initial assessment, offer men with LUTS a physical examination guided by urological symptoms and other medical conditions, an examination of the abdomen and external genitalia, and a digital rectal examination (DRE). [2010]

At initial assessment, ask men with bothersome LUTS to complete a urinary frequency volume chart. [2010]

At initial assessment, offer men with LUTS a urine dipstick test to detect blood, glucose, protein, leucocytes and nitrites. [2010]

At initial assessment, offer men with LUTS information, advice and time to decide if they wish to have prostate specific antigen (PSA) testing if:

- Their LUTS are suggestive of bladder outlet obstruction secondary to benign prostatic enlargement (BPE) or
- Their prostate feels abnormal on DRE or
- They are concerned about prostate cancer [2010]

Manage suspected prostate cancer in men with LUTS in line with the NGC summaries of the NICE guidelines [Prostate cancer: diagnosis and treatment](#) and [Suspected cancer: recognition and referral](#). [2010]

At initial assessment, offer men with LUTS a serum creatinine test (plus estimated glomerular filtration rate [eGFR] calculation) only if you suspect renal impairment (for example, the man has a palpable bladder, nocturnal enuresis, recurrent urinary tract infections or a history of renal stones). [2010]

Do not routinely offer cystoscopy to men with uncomplicated LUTS (that is, without evidence of bladder abnormality) at initial assessment. [2010]

Do not routinely offer imaging of the upper urinary tract to men with uncomplicated LUTS at initial assessment. [2010]

Do not routinely offer flow-rate measurement to men with LUTS at initial assessment. [2010]

Do not routinely offer a post void residual volume measurement to men with LUTS at initial assessment. [2010]

At initial assessment, give reassurance, offer advice on lifestyle interventions (for example, fluid intake) and information on their condition to men whose LUTS are not bothersome or complicated. Offer review if symptoms change. [2010]

Offer men referral for specialist assessment if they have bothersome LUTS that have not responded to conservative management or drug treatment. [2010]

Refer men for specialist assessment if they have LUTS complicated by recurrent or persistent urinary tract infection, retention, renal impairment that is suspected to be caused by lower urinary tract dysfunction, or suspected urological cancer. [2010]

Offer men considering any treatment for LUTS an assessment of their baseline symptoms with a validated symptom score (for example, the IPSS) to allow assessment of subsequent symptom change. [2010]

### Specialist Assessment

Specialist assessment refers to assessment carried out in any setting by a healthcare professional with specific training in managing LUTS in men.

Offer men with LUTS having specialist assessment an assessment of their general medical history to identify possible causes of LUTS, and associated comorbidities. Review current medication, including herbal and over-the-counter medicines to identify drugs that may be contributing to the problem. [2010]

Offer men with LUTS having specialist assessment a physical examination guided by urological symptoms and other medical conditions, an examination of the abdomen and external genitalia, and a DRE. [2010]

At specialist assessment, ask men with LUTS to complete a urinary frequency volume chart. [2010]

At specialist assessment, offer men with LUTS information, advice and time to decide if they wish to have PSA testing if:

- Their LUTS are suggestive of bladder outlet obstruction secondary to BPE or
- Their prostate feels abnormal on DRE or
- They are concerned about prostate cancer [2010]

Offer men with LUTS who are having specialist assessment a measurement of flow rate and post void residual volume. [2010]

Offer cystoscopy to men with LUTS having specialist assessment only when clinically indicated, for example if there is a history of any of the following:

- Recurrent infection
- Sterile pyuria
- Haematuria
- Profound symptoms
- Pain [2010]

Offer imaging of the upper urinary tract to men with LUTS having specialist assessment only when clinically indicated, for example if there is a history of any of the following:

- Chronic retention
- Haematuria
- Recurrent infection
- Sterile pyuria
- Profound symptoms
- Pain [2010]

Consider offering multichannel cystometry to men with LUTS having specialist assessment if they are considering surgery. [2010]

Offer pad tests to men with LUTS having specialist assessment only if the degree of urinary incontinence needs to be measured. [2010]

### Conservative Management

Explain to men with post micturition dribble how to perform urethral milking. [2010]

Offer men with storage LUTS (particularly urinary incontinence) temporary containment products (for example, pads or collecting devices) to achieve social continence until a diagnosis and management plan have been discussed. [2010]

Offer a choice of containment products to manage storage LUTS (particularly urinary incontinence) based on individual circumstances and in consultation with the man. [2010]

Offer men with storage LUTS suggestive of overactive bladder (OAB) supervised bladder training, advice on fluid intake, lifestyle advice and, if needed, containment products. [2010]

Inform men with LUTS and proven bladder outlet obstruction that bladder training is less effective than surgery. [2010]

Offer supervised pelvic floor muscle training to men with stress urinary incontinence caused by prostatectomy. Advise them to continue the exercises for at least 3 months before considering other options. [2010]

Refer for specialist assessment men with stress urinary incontinence. [2010]

Do not offer penile clamps to men with storage LUTS (particularly urinary incontinence). [2010]

Offer external collecting devices (for example, sheath appliances, pubic pressure urinals) for managing storage LUTS (particularly urinary incontinence) in men before considering indwelling catheterisation (see recommendation below). [2010]

Offer intermittent bladder catheterisation before indwelling urethral or suprapubic catheterisation to men with voiding LUTS that cannot be corrected by less invasive measures. [2010]

Consider offering long-term indwelling urethral catheterisation to men with LUTS:

- For whom medical management has failed and surgery is not appropriate and

- Who are unable to manage intermittent self-catheterisation or
- With skin wounds, pressure ulcers or irritation that are being contaminated by urine or
- Who are distressed by bed and clothing changes [2010]

If offering long-term indwelling catheterisation, discuss the practicalities, benefits and risks with the man and, if appropriate, his carer. [2010]

Explain to men that indwelling catheters for urgency incontinence may not result in continence or the relief of recurrent infections. [2010]

Consider permanent use of containment products for men with storage LUTS (particularly urinary incontinence) only after assessment and exclusion of other methods of management. [2010]

### Drug Treatment

Offer drug treatment only to men with bothersome LUTS when conservative management options have been unsuccessful or are not appropriate. [2010]

Take into account comorbidities and current treatment when offering men drug treatment for LUTS. [2010]

Offer an alpha blocker (alfuzosin, doxazosin, tamsulosin or terazosin) to men with moderate to severe LUTS. [2010]

Offer an anticholinergic to men to manage the symptoms of OAB. [2010]

Offer a 5-alpha reductase inhibitor to men with LUTS who have prostates estimated to be larger than 30 g or a PSA level greater than 1.4 ng/ml, and who are considered to be at high risk of progression (for example, older men). [2010]

Consider offering a combination of an alpha blocker and a 5-alpha reductase inhibitor to men with bothersome moderate to severe LUTS and prostates estimated to be larger than 30 g or a PSA level greater than 1.4 ng/ml. [2010]

Consider offering an anticholinergic as well as an alpha blocker to men who still have storage symptoms after treatment with an alpha blocker alone. [2010]

Consider offering a late afternoon loop diuretic to men with nocturnal polyuria. (Note: At the time of publication [June 2015], loop diuretics [for example, furosemide] did not have a UK marketing authorisation for this indication. Informed consent should be obtained and documented. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#)  for further information.) [2010]

Consider offering oral desmopressin to men with nocturnal polyuria if other medical causes<sup>3</sup> have been excluded and they have not benefited from other treatments. Measure serum sodium 3 days after the first dose. If serum sodium is reduced to below the normal range, stop desmopressin treatment. (Note: At the time of publication [June 2015], desmopressin did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#)  for further information. Medical conditions that can cause nocturnal polyuria symptoms include diabetes mellitus, diabetes insipidus, adrenal insufficiency, hypercalcaemia, liver failure, polyuric renal failure, chronic heart failure, obstructive apnoea, dependent oedema, pyelonephritis, chronic venous stasis, sickle cell anaemia. Medications that can cause nocturnal polyuria symptoms include calcium channel blockers, diuretics, and selective serotonin reuptake inhibitors [SSRIs]). [2010]

Do not offer phosphodiesterase-5-inhibitors solely for the purpose of treating LUTS in men, except as part of a randomised controlled trial. [new 2015]

### Review

Discuss active surveillance (reassurance and lifestyle advice without immediate treatment and with regular follow-up) or active intervention (conservative management, drug treatment or surgery) for:

- Men with mild or moderate bothersome LUTS
- Men whose LUTS fail to respond to drug treatment [2010]

Review men taking drug treatments to assess symptoms, the effect of the drugs on the patient's quality of life and to ask about any adverse effects from treatment. [2010]

Review men taking alpha blockers at 4 to 6 weeks and then every 6 to 12 months. [2010]

Review men taking 5-alpha reductase inhibitors at 3 to 6 months and then every 6 to 12 months. [2010]

Review men taking anticholinergics every 4 to 6 weeks until symptoms are stable, and then every 6 to 12 months. [2010]

### Surgery for Voiding Symptoms

For men with voiding symptoms, offer surgery only if voiding symptoms are severe or if drug treatment and conservative management options have been unsuccessful or are not appropriate. Discuss the alternatives to and outcomes from surgery. [2010]

If offering surgery for managing voiding LUTS presumed secondary to BPE, offer monopolar or bipolar transurethral resection of the prostate (TURP), monopolar transurethral vaporisation of the prostate (TUVF) or holmium laser enucleation of the prostate (HoLEP). Perform HoLEP at a centre specialising in the technique, or with mentorship arrangements in place. [2010]

Offer transurethral incision of the prostate (TUIP) as an alternative to other types of surgery to men with a prostate estimated to be smaller than 30 g. [2010]

Only offer open prostatectomy as an alternative to TURP, TUVF or HoLEP to men with prostates estimated to be larger than 80 g. [2010]

If offering surgery for managing voiding LUTS presumed secondary to BPE, do not offer minimally invasive treatments (including transurethral needle ablation [TUNA], transurethral microwave thermotherapy [TUMT], high-intensity focused ultrasound [HIFU], transurethral ethanol ablation of the prostate [TEAP] and laser coagulation) as an alternative to TURP, TUVF or HoLEP. [2010]

If offering surgery for managing voiding LUTS presumed secondary to BPE, only consider offering botulinum toxin injection into the prostate as part of a randomised controlled trial. [2010]

If offering surgery for managing voiding LUTS presumed secondary to BPE, only consider offering laser vaporisation techniques, bipolar TUVF or monopolar or bipolar transurethral vaporisation resection of the prostate (TUVRP) as part of a randomised controlled trial that compares these techniques with TURP. [2010]

### Surgery for Storage Symptoms

If offering surgery for storage symptoms, consider offering only to men whose storage symptoms have not responded to conservative management and drug treatment. Discuss the alternatives of containment or surgery. Inform men being offered surgery that effectiveness, side effects and long-term risk are uncertain. [2010]

If considering offering surgery for storage LUTS, refer men to a urologist to discuss:

- The surgical and non-surgical options appropriate for their circumstances and
- The potential benefits and limitations of each option, particularly long-term results [2010]

Consider offering cystoplasty to manage detrusor overactivity only to men whose symptoms have not responded to conservative management or drug treatment and who are willing and able to self-catheterise. Before offering cystoplasty, discuss serious complications (that is, bowel disturbance, metabolic acidosis, mucus production and/or mucus retention in the bladder, urinary tract infection and urinary retention). [2010]

Consider offering bladder wall injection with botulinum toxin to men with detrusor overactivity only if their symptoms have not responded to conservative management and drug treatments and the man is willing and able to self-catheterise. (Note: At the time of publication [June 2015], botulinum toxin A and botulinum toxin B did not have UK marketing authorisations for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#)  for further information.) [2010]

Consider offering implanted sacral nerve stimulation to manage detrusor overactivity only to men whose symptoms have not responded to conservative management and drug treatments. [2010]

Do not offer myectomy to men to manage detrusor overactivity. [2010]

Consider offering intramural injectables, implanted adjustable compression devices and male slings to manage stress urinary incontinence only as part of a randomised controlled trial. [2010]

Consider offering urinary diversion to manage intractable urinary tract symptoms only to men whose symptoms have not responded to conservative

management and drug treatments, and if cystoplasty or sacral nerve stimulation are not clinically appropriate or are unacceptable to the patient. [2010]

Consider offering implantation of an artificial sphincter to manage stress urinary incontinence only to men whose symptoms have not responded to conservative management and drug treatments. [2010]

### Treating Urinary Retention

Immediately catheterise men with acute retention. [2010]

Offer an alpha blocker to men for managing acute urinary retention before removal of the catheter. [2010]

Consider offering self- or carer-administered intermittent urethral catheterisation before offering indwelling catheterisation for men with chronic urinary retention. [2010]

Carry out a serum creatinine test and imaging of the upper urinary tract in men with chronic urinary retention (residual volume greater than 1 litre or presence of a palpable/percussable bladder). [2010]

Catheterise men who have impaired renal function or hydronephrosis secondary to chronic urinary retention. [2010]

Consider offering intermittent or indwelling catheterisation before offering surgery in men with chronic urinary retention. [2010]

Consider offering surgery on the bladder outlet without prior catheterisation to men who have chronic urinary retention and other bothersome LUTS but no impairment of renal function or upper renal tract abnormality. [2010]

Consider offering intermittent self- or carer-administered catheterisation instead of surgery in men with chronic retention who you suspect have markedly impaired bladder function. [2010]

Continue or start long-term catheterisation in men with chronic retention for whom surgery is unsuitable. [2010]

Provide active surveillance (post void residual volume measurement, upper tract imaging and serum creatinine testing) to men with non-bothersome LUTS secondary to chronic retention who have not had their bladder drained. [2010]

### Alternative and Complementary Therapies

Do not offer homeopathy, phytotherapy or acupuncture for treating LUTS in men. [2010]

### Providing Information

Ensure that, if appropriate, men's carers are informed and involved in managing their LUTS and can give feedback on treatments. [2010]

Make sure men with LUTS have access to care that can help with:

- Their emotional and physical conditions and
- Relevant physical, emotional, psychological, sexual and social issues [2010]

Provide men with storage LUTS (particularly incontinence) containment products at point of need, and advice about relevant support groups. [2010]

### Definitions

#### Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group (GDG) makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the GDG is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

#### *Interventions That Must (or Must Not) Be Used*

The GDG usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally 'must' (or 'must not') is used if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

#### *Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation*

The GDG uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. Similar forms of words (for example, 'Do not offer...') are used when the GDG is confident that an intervention will not be of benefit for most patients.

#### *Interventions That Could Be Used*

The GDG uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

#### *Recommendation Wording in Guideline Updates*

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009).

## Clinical Algorithm(s)

The following clinical algorithms are provided in the full version of the 2010 guideline (see the "Availability of Companion" Documents" field):

- Diagnosis
- Chronic urinary retention (specialist care)
- Predominant storage symptoms
- Predominant voiding symptoms

In addition, a National Institute for Health and Care Excellence (NICE) care pathway titled "Lower Urinary Tract Symptoms in Men Overview" is available from the [NICE Web site](#) .

## Scope

### Disease/Condition(s)

Diseases or conditions that result in lower urinary tract symptoms (LUTS), including:

- Benign prostate enlargement
- Prostatitis
- Urinary tract infections
- Urological/renal cancers
- Detrusor muscle weakness
- Neurological disease

### Guideline Category

Diagnosis

Evaluation

Management

Treatment

### Clinical Specialty

Family Practice

Geriatrics

Infectious Diseases

Internal Medicine

Oncology

Surgery

Urology

## Intended Users

Advanced Practice Nurses

Health Care Providers

Hospitals

Nurses

Patients

Pharmacists

Physical Therapists

Physician Assistants

Physicians

## Guideline Objective(s)

- To prepare a guideline on the assessment, investigation, management and onward referral of men with lower urinary tract symptoms (LUTS) (including male incontinence) within primary care
- To advise on the effective evidence-based management of LUTS in men

## Target Population

- Adult men (18 years or older) with a clinical working diagnosis of lower urinary tract symptoms (LUTS)
- Men who have a higher prevalence of LUTS or may be at higher risk, including:
  - Older men
  - Men who are of black origin

## Interventions and Practices Considered

### Diagnosis/Evaluation

1. Initial assessment
  - Patient history and physical exam
  - International Prostate Symptom Score (IPSS) assessment
  - Digital rectal examination (DRE)
  - Urinary frequency volume chart
  - Urine dipstick test (blood, glucose, protein, leucocytes, nitrites)



- Prostate specific antigen (PSA) testing
  - Serum creatinine and estimated glomerular filtration rate
2. Specialist assessment
    - Urinary flow rate
    - Post-void residual volume
    - Cystoscopy
    - Imaging of upper urinary tract
    - Multichannel cystometry
    - Pad tests

## Management/Treatment

1. Monitoring of chronic lower urinary tract symptoms (LUTS) (conservative management)
2. Referral to specialist
3. Non-pharmacological interventions
  - Urethral milking
  - Active surveillance
  - Containment/collecting devices (such as catheters, pads, and clamps)
4. Drug treatment
  - Alpha blockers
  - Anticholinergics
  - 5-alpha reductase inhibitors
  - Combination therapy
  - Loop diuretics
  - Desmopressin
  - Phosphodiesterase-5-inhibitors (PDE5Is) (not recommended solely for treating LUTS)
5. Surgical interventions for voiding symptoms
  - Monopolar or bipolar transurethral resection of the prostate (TURP)
  - Monopolar transurethral vaporisation of the prostate (TUVP)
  - Holmium laser enucleation of the prostate (HoLEP)
  - Transurethral incision of the prostate (TUIP)
  - Open prostatectomy
  - Botulinum toxin injection into prostate (not recommended in patients with benign prostate enlargement except as part of a randomised controlled trial)
6. Surgery for storage symptoms
  - Cystoplasty
  - Bladder wall injection with botulinum toxin
  - Implanted sacral nerve stimulation
  - Myectomy (not recommended for detrusor overactivity)
  - Intramural injectables, implanted adjustable compression devices and male slings to manage stress urinary incontinence only as part of a randomised controlled trial
  - Urinary diversion
  - Implantation of an artificial sphincter to manage stress urinary incontinence
7. Treatment of urinary retention
  - Immediate catheterisation for acute retention
  - Long-term intermittent or indwelling catheterisation
  - Alpha blocker therapy
  - Surgery
8. Active surveillance with regular follow-up
9. Alternative and complementary therapies such as homeopathy, phytotherapy, or acupuncture (not recommended)
10. Condition-specific information, support, and communication needs of patients, carers, and families

## Major Outcomes Considered

- Prognostic value of diagnostic tests (specificity, sensitivity, likelihood ratios, pre and post-test probabilities, negative and positive predictive values)
- Correlation of prostate specific antigen (PSA) at baseline with International Prostate Symptom Score (IPSS) at follow-up
- Symptomatic improvement
- Quality of life
- Maximum urinary flow rate (Qmax)
- Incontinence episodes
- Adverse effects
- Patient views for diagnostic studies and conservative interventions
- Mortality
- Cost-effectiveness

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) for Acute and Chronic Conditions on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

#### 2010 Guideline

Literature Search

#### *Clinical Literature Search*

The aim of the literature search was to find "evidence within the published literature" to answer the clinical questions identified. Reviewers searched clinical databases using relevant medical subject headings and free-text terms. Search filters were used to limit searches to particular study types where applicable. Non-English language studies and abstracts were not excluded from the search but the articles were not reviewed.

Initial searches for each section were performed when the literature was needed for the review. Each search was updated twice nearer the end of guideline development period: once at the beginning of April and then finally, 17 June 2009. No papers after this date were considered.

The following databases were searched:

- The Cochrane Library up to Issue 2 2009
- Medline 1950-2009 (OVID)
- EMBASE 1980-2009 (OVID)
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) 1982-2009 (Dialog Datastar, later NLH Search 2.0, update searches in EBSCO) - searched for questions relating to patient education and views only
- PsycINFO 1800s-2009 (NLH Search 2.0, update searches in Ovid) - searched for questions relating to patient education and views only

There was no systematic attempt to search for grey literature or unpublished literature although all stakeholder references were followed up. Reviewers searched for guidelines and reports via relevant urological Web sites including those listed below.

- Constituent Web sites of the Guidelines International Network ([www.g-i-n.net](http://www.g-i-n.net) )
- National Guideline Clearinghouse (NGC) ([www.guideline.gov](http://www.guideline.gov) )
- NICE ([www.nice.org.uk](http://www.nice.org.uk) )

- National Institutes of Health Consensus Development Program ([www.consensus.nih.gov](http://www.consensus.nih.gov) )
- National Library for Health (<http://www.nice.org.uk/about/what-we-do/evidence-services/journals-and-databases> )

### *Economic Literature Search*

Published economic evidence was obtained from a systematic search of the following databases:

- The Cochrane Library up to Issue 3 2008
- Medline 1950-2009 (OVID)
- EMBASE 1980-2009 (OVID)
- Health economic and evaluations database (HEED) up to August 2008 (access was no longer available after that date)

The information specialists used the same search strategy as for the clinical questions, using an economics filter in the place of a systematic review or randomised controlled trial filter. Each database was searched from its start. Each search was updated twice nearer the end of guideline development period: once at the beginning of April and then finally, 17 June 2009. Papers identified after this date were not considered. Search strategies can be found in Appendix C in the full guideline appendices (see the "Availability of Companion Documents" field).

Each search strategy was designed to find any applied study estimating the cost or cost-effectiveness of an included intervention, quality of life literature, and literature relating to economic modelling. A health economist reviewed the abstracts. Relevant references in the bibliographies of reviewed papers were also identified and reviewed.

### *Literature Reviewing Process*

#### *Clinical Literature Reviewing Process*

References identified by the systematic literature search were screened for appropriateness by title and abstract by an information scientist and systematic reviewer. Studies were selected that reported one or more of the outcomes listed in section 2.4 of the full version of the guideline. Selected studies were ordered and assessed in full by the National Clinical Guideline Centre (NCGC) team using agreed inclusion/exclusion criteria specific to the guideline topic, and using NICE methodology quality assessment checklists appropriate to the study design. Further references suggested by the Guideline Development Group (GDG) were assessed in the same way.

#### *Economic Literature Reviewing Process*

Economic studies identified in the systematic search were excluded from the review if

- The study did not contain any original data on cost or cost-effectiveness (that is, it was a review or a clinical paper)
- The study population did not comply with the inclusion criteria as established in the clinical effectiveness review methods
- The analysis was not incremental and was not described adequately to allow incremental analysis (so studies reporting only average cost-effectiveness ratios were excluded unless they provided data to allow the calculation of incremental cost-effectiveness ratios)
- The study was a non-UK cost-analysis
- The study was a letter or written in a foreign language

### 2015 Update

#### *Clinical Evidence Review*

The aim of the review was to assess the effectiveness of phosphodiesterase-5-inhibitors (PDE5Is) in the management of lower urinary tract symptoms (LUTS) in men compared to placebo, other pharmacological, surgical and conservative management.

A systematic search was conducted in August 2014 (see Appendix D of the addendum [see the "Availability of Companion Documents" field]), which identified 543 articles. The titles and abstracts were screened and 64 articles were identified as potentially relevant. Full text versions of the articles were obtained and reviewed against the criteria specified in the review protocol (see Appendix C of the guideline addendum).

#### *Health Economics*

The Committee was required to make decisions based on the best available evidence of both clinical and cost-effectiveness. An additional search was undertaken using the same clinical search terms with an economic evaluations filter to identify studies assessing the cost-effectiveness or cost-utility of PDE5Is for the treatment of LUTS (see Appendix J of the guideline addendum). The same criteria were used as for the clinical review. The search retrieved 286 articles. The titles and abstracts were screened for possible inclusion.

# Number of Source Documents

## 2010 Guideline

Studies meeting inclusion criteria: 260

## 2015 Update

### Clinical Evidence Review

21 articles were included in the review (6 were included in the original 2010 guideline and 15 new articles were identified). The review flow chart for this review is in Appendix E of the guideline addendum (see the "Availability of Companion Documents" field).

### Health Economics

The search retrieved 286 articles. The titles and abstracts were screened for possible inclusion, and no articles were selected for further examination of the full-text version. A review flowchart is provided in Appendix K of the guideline addendum.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

### Levels of Evidence for Studies of Accuracy of Diagnostic Tests

Ia - Systematic review with homogeneity<sup>a</sup> of level-1 studies<sup>b</sup>

Ib - Level-1 studies<sup>b</sup>

II - Level-2 studies<sup>c</sup>; systematic reviews of level-2 studies

III - Level-3 studies<sup>d</sup>; systematic reviews of level-3 studies

IV - Consensus, expert committee reports or opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research or "first principles"

<sup>a</sup>Homogeneity indicates there are no or minor variations in the directions and degrees of results between individual studies included in the systematic review

<sup>b</sup>Level-1 studies:

1. Use a blind comparison of the test with a reference standard (gold standard)
2. Are conducted in a sample of patients that reflects the population to whom the test would apply

<sup>c</sup>Level-2 studies have only one of the following:

1. Narrow population (sample does not reflect the population to whom the test would apply)
2. A poor reference standard (where tests are not independent)
3. The comparison between the test and reference standard is not masked
4. A case-control study design

<sup>d</sup>Level-3 studies have two or three of the above features

### Overall Quality of Outcome Evidence in Grading of Recommendations Assessment, Development and Evaluation (GRADE)

Quality Element	Description
High	Further research is very unlikely to change confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very low	Any estimate of effect is very uncertain.

## Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) for Acute and Chronic Conditions on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

### 2010 Guideline

#### Assessing Quality of Evidence

Two stages of quality assessment were conducted. At the first stage, studies found through the systematic search are quality assessed and only included in the review and meta-analysis if they met some or all of the quality criteria. Data from these studies are then extracted and the outcomes of interest are then pooled. At the second stage, the quality of evidence for each of these outcomes is then quality assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

#### *Quality Assessment for Inclusion of Studies*

All studies are quality assessed before being included as part of the systematic review. The criteria for assessment for different types of studies are listed in Section 2.6.1 of the full version of the guideline.

#### *Grading of Recommendations Assessment, Development and Evaluation*

The evidence for outcomes from studies which passed the quality assessment were evaluated and presented using "GRADE Toolbox" developed by the international GRADE Working Group (<http://www.gradeworkinggroup.org> ). The software (GRADEpro) developed by the GRADE Working Group was used to assess pooled outcome data using individual study quality assessments and results from meta-analysis.

The summary of findings was presented as two separate tables (see the full version of the guideline). The Clinical Study Characteristics table includes details of the quality assessment while the "Clinical Summary of Findings" table includes pooled outcome data, an absolute measure of intervention effect calculated and the summary of quality of evidence for that outcome. In this table, the columns for intervention and control indicate pooled sample size for continuous outcomes. For binary outcomes such as number of patients with an adverse event, the event rates (n/N) are shown with percentages. Reporting or publication bias was considered in the quality assessment but not included in the Clinical Study Characteristics table because this was a rare reason for downgrading an outcome in this guideline.

#### NICE Economic Profile

Since GRADE was not originally designed for economic evidence, the NICE economic profile has been used to present cost and cost-effectiveness estimates from published studies or analyses conducted for the guideline. As for the clinical evidence, the economic evidence has separate tables for the quality assessment and for the summary of results. The quality assessment is based on two criteria – limitations and

applicability (see Table 2-7 in the full version of the guideline) and each criterion is graded using the levels in Table 2-8 and Table 2-9 of the full version of the guideline.

An overall score of the evidence is not given as it is not clear how the quality elements could be summarised into a single quality rating.

A summary of results is presented for each study including:

- incremental cost
- incremental effectiveness
- incremental cost-effectiveness ratio
- uncertainty

## Literature Reviewing Process

### *Economic Literature Reviewing Process*

Included papers were reviewed by a health economist. In the evidence tables, costs are reported as in the paper. However, where costs were in a currency other than pounds sterling, the results were converted into pounds sterling using the appropriate purchasing power parity for the study year.

Studies from all over the world were included in the review, however, overseas studies were used with caution since resource use and especially unit costs vary considerably. Particular caution is applied to studies with predominantly private health insurance (for example, USA or Switzerland) where unit costs may be much higher than in the UK and to developing countries where costs may be much lower.

Each study was categorised as one of the following: cost analysis, cost-effectiveness analysis, cost-utility analysis (that is, cost-effectiveness analysis with effectiveness measured in terms of quality-adjusted life-years [QALYs]), or cost consequences analysis. One 'cost benefit analysis' (study that puts a monetary value on health gain) was found, but it was not included for methodological reasons.

Models are analogous to systematic reviews because they pool evidence from a number of different studies and therefore if well-conducted they should out-rank studies based on a single randomised controlled trial. Statistical significance is not usually applicable to models and uncertainty is explored using sensitivity analysis instead. Hence the results reported in economic GRADE tables, evidence tables and write-up may not necessarily imply statistical significance.

### *Cost-effectiveness Modelling*

The details of the economic models are described in Appendix F in the full guideline appendices (see the "Availability of Companion Documents" field).

## Methods of Combining Studies

Where possible, meta-analyses were conducted to combine the results of studies for each clinical question using Cochrane Review Manager (RevMan5) software. Fixed-effects (Mantel-Haenszel) techniques were used to calculate risk ratios (relative risk) for the binary outcomes: number of incontinent patients or adverse events, and the continuous outcome for endpoint or change from baseline International Prostate Symptom Score (IPSS) score, quality of life question from IPSS score and maximum urinary flow rate (Q<sub>max</sub>) was analysed using an inverse variance method for pooling weighted mean differences. Statistical heterogeneity was assessed by considering the chi-squared test for significance at  $p < 0.05$  or an I-squared inconsistency statistic of  $\geq 50\%$  to indicate significant heterogeneity.

Where significant heterogeneity was present reviewers carried out predefined subgroup analyses for: the severity or main type of symptoms experienced by participants recruited into the studies, treatment protocols and length of follow-up. Sensitivity analysis based on the quality of studies was also carried out if there were differences (e.g., open label vs. masked studies). Assessments of potential differences in effect between subgroups were based on the chi-squared tests for heterogeneity statistics between subgroups. If no sensitivity analysis was found to completely resolve statistical heterogeneity then a random effects (DerSimonian and Laird) model was employed to provide a more conservative estimate of the effect.

The standard deviations of continuous outcomes were required for imputation for meta-analysis. However, this was not reported in many studies. In such cases, calculation based on methods outlined in section 7.7.3 of the Cochrane Handbook (February 2008). 'Data extraction for continuous outcomes' were applied to estimate the standard deviations if p values of the difference between two means, 95% confidence intervals or standard error of the mean (SEM) had been reported. Where p values were reported as 'less than', a conservative approach was undertaken. For example, if p value was reported as ' $p \leq 0.001$ ', the calculations for standard deviations will be based on a p value of 0.001. If these statistical measures were not available, then the methods described in Section 16.1.3 of the Cochrane Handbook (February 2008). 'Missing standard deviations' were

applied as the last resort.

For binary outcomes, absolute event rates were also calculated using the GRADEpro software using event rate in the control arm of the pooled results.

### Grading of Quality of Evidence for Outcomes

After results were pooled, the overall quality of evidence for each outcome was considered using the GRADE system. The following is the procedure adopted when using GRADE:

1. The evidence for all outcomes start with a HIGH quality rating as only randomised controlled trials were considered.
2. The rating was then downgraded for the specified criteria: Study limitations, inconsistency, indirectness, imprecision and reporting bias. These criteria are detailed in Section 2.9.1 of the full version of the guideline.
3. The downgrade marks are then summed. Each quality element being considered as having 'serious' or 'very serious' risk of bias were rated down -1 or -2 points respectively. All studies started as HIGH and the quality became MODERATE, LOW or VERY LOW when 1, 2 or 3 points were deducted respectively.
4. The reasons or criteria used for downgrading were specified in the footnotes whenever possible.

The details of criteria used for each of the main quality elements are discussed further in Sections 2.9.1 to 2.9.4 of the full version of the guideline.

### 2015 Update

#### Clinical Evidence Review

- Lower urinary tract symptoms (LUTS) can be associated with erectile dysfunction (ED). ED only populations were excluded as the efficacy of phosphodiesterase-5-inhibitors (PDE5Is) on the symptoms of LUTS is the focus of this review. The original guideline had a subgroup for men of African family origin; this subgroup was included in this update. To capture information from the trials relevant to the population, it was agreed that the relevant baseline characteristics of age, polypharmacy and comorbidities would be extracted where available, to help inform decision making.
- The PDE5Is listed in the British National Formulary (BNF), and evaluated in this evidence review, include sildenafil, tadalafil and vardenafil. An experimental PDE5I (not listed in the BNF) was also identified and evaluated in this evidence review; this is UK-369,003, or Gisadenafil (U.S. Food and Drug Administration [FDA] Web site) and was used in two studies. At the current time (November 2014), tadalafil is the only PDE5I licensed for use in benign prostatic hyperplasia (BPH)/LUTS.
- The comparators identified from the searches and included in this review are placebo, alpha blockers and antimuscarinics. With regards to the comparison to alpha blockers, two studies used suboptimal doses of Tamsulosin (0.2 mg/day), whereas the BNF recommends a dose of 0.4 mg/day.
- The topic specific members (TSMs) were asked to prioritise the patient important outcomes for LUTS using a ranking method (from 1 [most important] to 9 [least important]). The rankings from each TSM were then compared and the final ranking of outcomes was based on the most common ranking decision. There was general consensus that symptom scores, such as IPSS, was the most important outcome, followed by quality of life, voiding frequency and maximal urinary flow rate (Q<sub>max</sub>) and nocturia. It was agreed that the relevant adverse events had been captured in the outcomes.
- GRADE methodology was used to assess the quality of evidence. See the guideline addendum (see the "Availability of Companion Documents" field) for further details on GRADE methodology.

#### Health Economics

As no relevant published studies were found, and a new analysis was not conducted, the Committee made a qualitative judgement about cost-effectiveness by considering expected differences in resource use between options and relevant UK National Health Service (NHS) unit costs, alongside the results of the clinical review of effectiveness evidence. The qualitative approach to economic impacts was appropriate in this circumstance as there was evidence showing that the treatment effect does not reach a clinically important difference. The UK NHS costs reported in the guideline were those presented to the Committee and they were correct at the time recommendations were drafted; they may have been revised subsequently by the time of publication.

## Methods Used to Formulate the Recommendations

#### Expert Consensus

# Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) for Acute and Chronic Conditions on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

## 2010 Guideline

### Who Developed This Guideline?

A multidisciplinary Guideline Development Group (GDG) comprising professional group members and consumer representatives of the main stakeholders developed this guideline. NICE funds the National Collaborating Centre for Acute Care (NCC-AC) and latterly the NCGC and thus supported the development of this guideline. The GDG was convened by the NCC-AC and chaired by Professor Christopher Chapple in accordance with guidance from the NICE.

The GDG met every 6 to 8 weeks during the development of the guideline. Staff from the NCC-AC/NCGC provided methodological support and guidance for the development process. They undertook systematic searches, retrieval and appraisal of the evidence and drafted the guideline.

### Developing the Clinical Questions

Clinical questions were developed to guide the literature searching process and to facilitate the development of recommendations by the GDG. They were drafted by the review team and refined and validated by the GDG. The questions were based on the scope (see Appendix A in the full guideline appendices [see the "Availability of Companion Documents" field]).

### Development of the Recommendations

Over the course of the guideline development process, the GDG was presented with the following:

- Evidence tables of the clinical and economic evidence reviewed. All evidence tables are in Appendix D in the full guideline appendices.
- Summary of clinical evidence and quality (as presented in section write ups)
- Forest plots of meta-analyses (see Appendix E in the full guideline appendices)
- A description of the methods and results of the cost-effectiveness analysis (see Appendix F in the full guideline appendices)

Recommendations were drafted on the basis of this evidence whenever it was available.

When clinical and economic evidence was absent, of poor quality or conflicting, the GDG drafted recommendations based on their expert opinion. This may be done through discussions in the GDG, or methods of formal consensus may be applied. The considerations for making these consensus based recommendations include the balance between potential harms and benefits, economic or implications compared to the benefits, current practices, recommendations made in other relevant guidelines, patient preferences and equality issue. The GDG may also consider whether the uncertainty is sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation (see Section 2.11 in the full version of the guideline). The main considerations specific to each recommendation are outlined in the Linking Evidence to Recommendation Section accompanying these recommendations.

The GDG added supporting recommendations whenever it was necessary in order to improve clinical practice. The supporting recommendations were not derived from clinical questions and were based on GDG expert opinion. The process and considerations for making these supporting recommendations are similar to situations where evidence is lacking or of poor quality, as outlined above.

The development of the recommendations required several steps:

- Whenever possible, a preliminary draft recommendation was presented by NCGC staff after each summary of evidence presentation during GDG meetings. This draft was discussed and modified by the GDG to form the first draft recommendation.
- Where necessary, NCGC staff suggested modifications to the draft recommendations as a result of the discussion and in the light of NICE guidance on writing recommendations.
- Towards the end of the guideline development process, a list of all the draft recommendations was sent to the GDG members. The GDG members independently completed a consensus exercise to feedback comments and level of agreement on each recommendation. This procedure allowed the NCGC to verify the level of agreement between the GDG members.
- All GDG feedback was collated and circulated again to the GDG. The recommendations which did not have unanimous agreement were discussed again during a GDG meeting before being finalised.
- During the writing up phase of the guideline, the GDG could further refine each recommendation working in subgroups on each chapter.



- NCGC staff verified the consistency of all recommendations across the guideline.

The GDG then developed care pathway algorithms according to the recommendations (see Appendix C of the original guideline document).

## 2015 Update

These guidelines are updated using a standing Committee of healthcare professionals, research methodologists and lay members from a range of disciplines and localities. For the duration of the update the core members of the Committee are joined by up to 5 additional members who have specific expertise in the topic being updated, referred to as 'topic-specific members'.

The NICE guideline on the management of lower urinary tract symptoms (LUTS) in men (NICE clinical guideline CG97) was reviewed in July 2014 as part of NICE's routine surveillance programme to decide whether it required updating. The surveillance report identified new evidence relating to one area of the guidance:

- The use of phosphodiesterase-5-inhibitors (PDE5Is) for the treatment of lower urinary tract symptoms (LUTS) in men

The review question that the Committee considered was:

- What is the clinical and cost-effectiveness of PDE5Is alone in the treatment of LUTS?

## Methods

This update was developed based on the process and methods described in The guidelines manual 2012 (see the "Availability of Companion Documents" field). Where there are deviations from the process and methods, these are clearly stated in the [Interim process and methods guide for updates pilot programme 2013](#) .

# Rating Scheme for the Strength of the Recommendations

## Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group (GDG) makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the GDG is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

## Interventions That Must (or Must Not) Be Used

The GDG usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally 'must' (or 'must not') is used if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

## Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation

The GDG uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. Similar forms of words (for example, 'Do not offer...') are used when the GDG is confident that an intervention will not be of benefit for most patients.

## Interventions That Could Be Used

The GDG uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

## Recommendation Wording in Guideline Updates

The National Institute for Health and Care Excellence (NICE) began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of The guidelines manual (January 2009).

# Cost Analysis

## 2010 Guideline

### Cost-effectiveness Analysis

Two original cost-effectiveness analyses were carried out to answer the clinical questions on transurethral resection of the prostate (TURP) vs. laser, and the clinical question on alpha-blockers alone or in combination with 5-alpha reductase-inhibitors. Throughout the guideline the guideline developers refer to these two analyses respectively as "National Clinical Guidelines Center (NCGC) Surgery Model" and "NCGC Combination Model".

The following general principles were adhered to:

- The Guideline Development Group (GDG) was consulted during the construction and interpretation of the model.
- When published data was not available expert opinion was used to populate the model.
- Model assumptions were reported fully and transparently.
- The results were subject to sensitivity analysis and limitations were discussed.
- The developers followed the methods of the National Institute for Health and Care Excellence (NICE) reference case. Therefore, costs were calculated from a health services perspective. Health gain was measured in terms of quality-adjusted life-years (QALYs) gained. Both future costs and QALYs were discounted at 3.5%.
- The model employed a cost-effectiveness threshold of £20,000 per QALY gained.
- The model was peer-reviewed by another health economist at the NCGC.

The cost-effectiveness analyses were conducted using TreeAge Pro 2008.

The details of the economic models are described in Appendix F in the full guideline appendices (see the "Availability of Companion Documents" field).

## 2015 Update

No published economic evaluations were identified in the literature.

An original model was developed for the 2010 guideline that compared alpha-blockers with alpha-blockers plus 5-alpha-reductase-inhibitors. The 2010 model used an improvement in International Prostate Symptom Score (IPSS) of 3 points to distinguish between treatment success and treatment failure. The meta-analysis of all phosphodiesterase-5-inhibitors (PDE5Is) for the present systematic review found a mean improvement in IPSS of 1.78 (95% confidence interval [CI] 1.01 to 2.55). The 2010 model was not adapted for the present guideline update to include PDE5Is because none of the simulated cohort would have been considered a treatment success. The Committee considered that one study found a 4.4 (95% CI 1.87 to 6.93) point improvement in IPSS for sildenafil compared with placebo. The findings of this study were of limited usefulness because they were inconsistent with the 9 studies on other PDE5Is that reported this outcome, it is of very low quality, and there is likely to be confounding with improvements in erectile dysfunction (ED) as opposed to improvements in lower urinary tract symptoms (LUTS) alone. This study was considered by the 2010 GDG and PDE5Is were excluded from the economic modelling conducted at the time.

The Committee considered the cost of PDE5Is, alpha-blockers and 5-alpha-reductase inhibitors. Tadalafil 5 mg once-per-day is the only medicine currently licensed for benign prostatic hyperplasia. The annual cost of this treatment is £716.83 which is more costly than alpha-blockers and 5-alpha-reductase inhibitors. Vardenafil has a similar cost as tadalafil. Sildenafil, which is not currently licensed for LUTS, has an annual cost of £102.20 to £114.06 (25 mg to 100 mg). This is more costly than all, but one, alpha-blockers and more costly than one 5-alpha-reductase inhibitor.

The Committee concluded that PDE5Is are highly likely to not be cost-effective compared with currently recommended alpha-blockers because they have not been shown to be clinically effective and are more costly.

## Method of Guideline Validation

### External Peer Review

### Internal Peer Review

## Description of Method of Guideline Validation

## 2010 Guideline

The first draft of the 2010 guideline was posted on the National Institute for Health and Care Excellence (NICE) Web site for consultation between 28th August – 23rd October 2009 and registered stakeholders were invited to comment. The Guideline Development Group (GDG) responded to comments and an amended version of the guideline was produced.

## 2015 Update

The guideline was validated through two consultations.

1. The first draft of the guideline (the full guideline and NICE guideline) were consulted with stakeholders and comments were considered by the GDG.
2. The final consultation draft of the full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

## 2010 Guideline

Refer to the "Evidence statements" for each recommendation in the full version of the guideline (see the "Availability of Companion documents" field) for the type and quality of evidence for each recommendation.

## 2015 Update

Refer to the "Evidence to recommendations" section of the guideline addendum (see the "Availability of Companion documents" field) for the type and quality of evidence for the 2015 recommendation.

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

Appropriate diagnosis and treatment of lower urinary tract symptoms (LUTS) in men

Refer to the "Trade off between clinical benefits and harms" sections in the full version of the 2010 guideline and to the "Trade off between benefits and harms" sections of the 2015 guideline addendum (see the "Availability of Companion Documents" field) for benefits of specific intervention.

## Potential Harms

- The harms associated with digital rectal examination (DRE) are the short-term complications of embarrassment and transient discomfort.
- The harms associated with cystometry are the short-term complications of embarrassment, transient discomfort, haematuria and urinary tract infection.
- The harms associated with cystoscopy are discomfort, subsequent dysuria and bleeding, and the possibility of urinary tract infection or acute retention.
- Imaging tests are associated with some risks, including risks of radiation.
- The harms associated with various containment products include urinary infection, stone formation, skin problems and damage from improper use of penile clamps, sheaths and catheters.
- Harms of catheterisation include incorrect use of catheter and complications such as recurrent urinary tract infections, trauma to the urethra, accidental removal, recurrent blockage and stone formation. Patients may also be in pain or discomfort.

- Drug therapy is associated with adverse side effects and the potential harms from adding a new medication. Harms include adverse reactions and interactions with the other medications the patients take concomitantly. Polypharmacy is an important problem, especially for the elderly patients. Adverse effects of alpha blockers include orthostatic hypotension, dizziness, fatigue or asthenia, rhinitis, syncope, headache, erectile dysfunction, abnormal ejaculation. Adverse effects of 5-alpha reductase inhibitors include decreased libido, impotence and breast enlargement. Anticholinergic side effects include dry mouth. Loop diuretics may cause hypovolaemia and orthostatic hypotension. Potentially serious side-effects of desmopressin include hyponatraemia; the risk increases in elderly patients.
- Surgery carries the risk of both perioperative and long-term morbidity including sepsis, retention, urinary tract infection, bowel dysfunction, mucus production, metabolic problems, small malignant risk, and death.

Refer to the "Trade off between clinical benefits and harms" sections in the full version of the 2010 guideline and to the "Trade off between benefits and harms" section of the 2015 guideline addendum (see the "Availability of Companion Documents" field) for additional information about harms of specific interventions.

## Qualifying Statements

### Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of product characteristics of any drugs.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.
- The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual men.
- This guideline recommends some medicines for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) [ ] for further information. Where recommendations have been made for the use of medicines outside their licensed indications ('off-label use'), these medicines are marked with a footnote in the recommendations.
- Patients and healthcare professionals have rights and responsibilities as set out in the [National Health Service \(NHS\) Constitution for England](#) [ ] – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the [Department of Health's advice on consent](#) [ ]. If someone does not have capacity to make decisions, healthcare professionals should follow the [code of practice that accompanies the Mental Capacity Act](#) [ ] and the supplementary [code of practice on deprivation of liberty safeguards](#) [ ].
- NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in [Patient experience in adult NHS services](#) [ ].

## Implementation of the Guideline

### Description of Implementation Strategy

[Implementation tools and resources](#) [ ] to help put the guideline into practice are also available.

The following recommendations were identified as priorities for implementation in the 2010 guideline and have not been changed in the 2015 update.

### Key Priorities for Implementation

#### Initial Assessment

At initial assessment, offer men with lower urinary tract symptoms (LUTS) an assessment of their general medical history to identify possible causes of LUTS, and associated comorbidities. Review current medication, including herbal and over-the-counter medicines, to identify drugs that may be contributing to the problem. [2010]

At initial assessment, offer men with LUTS a physical examination guided by urological symptoms and other medical conditions, an examination of the abdomen and external genitalia, and a digital rectal examination (DRE). [2010]

At initial assessment, ask men with bothersome LUTS to complete a urinary frequency volume chart. [2010]

Refer men for specialist assessment if they have LUTS complicated by recurrent or persistent urinary tract infection, retention, renal impairment that is suspected to be caused by lower urinary tract dysfunction, or suspected urological cancer. [2010]

#### Conservative Management

Offer men with storage LUTS (particularly urinary incontinence) temporary containment products (for example, pads or collecting devices) to achieve social continence until a diagnosis and management plan have been discussed. [2010]

Offer men with storage LUTS suggestive of overactive bladder (OAB) supervised bladder training, advice on fluid intake, lifestyle advice and, if needed, containment products. [2010]

#### Surgery for Voiding Symptoms

If offering surgery for managing voiding LUTS presumed secondary to benign prostate enlargement (BPE), offer monopolar or bipolar transurethral resection of the prostate (TURP), monopolar transurethral vaporisation of the prostate (TUVF) or holmium laser enucleation of the prostate (HoLEP). Perform HoLEP at a centre specialising in the technique, or with mentorship arrangements in place. [2010]

If offering surgery for managing voiding LUTS presumed secondary to BPE, do not offer minimally invasive treatments (including transurethral needle ablation [TUNA], transurethral microwave thermotherapy [TUMT], high-intensity focused ultrasound [HIFU], transurethral ethanol ablation of the prostate [TEAP] and laser coagulation) as an alternative to TURP, TUVF or HoLEP (see Section 1.5.2 in the original guideline document). [2010]

#### Providing Information

Make sure men with LUTS have access to care that can help with:

- Their emotional and physical conditions and
- Relevant physical, emotional, psychological, sexual and social issues [2010]

Provide men with storage LUTS (particularly incontinence) containment products at point of need, and advice about relevant support groups. [2010]

## Implementation Tools

### Clinical Algorithm

### Foreign Language Translations

### Mobile Device Resources

### Patient Resources

### Resources

### Slide Presentation

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

Living with Illness

## IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

National Clinical Guideline Centre for Acute and Chronic Conditions. Lower urinary tract symptoms in men: assessment and management. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Jun. 38 p. (Clinical guideline; no. 97).

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2010 May (revised 2015 Jun)

### Guideline Developer(s)

National Clinical Guideline Centre for Acute and Chronic Conditions - National Government Agency [Non-U.S.]

### Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

### Guideline Committee

Guideline Development Group

### Composition of Group That Authored the Guideline

## 2010 Guideline

*Guideline Development Group Members:* Professor Christopher Chapple (*Chair*), Consultant Urological Surgeon, The Royal Hallamshire Hospital, Sheffield; Ms Angela Billington, Director of Continence Services, Bournemouth and Poole Community Health Services; Mr Paul Joachim, Patient Member, Chair of the Patient Advisory board, The Bladder and Bowel Foundation (InContact); Mr Thomas Ladds, Urology Specialist Nurse Practitioner, Central Manchester Hospitals NHS Trust (until February 2009); Mr Roy Latham, Patient Member, Member of Royal College of Physicians Patient Carer Network; Mr Malcolm Lucas, Consultant Urological Surgeon, Abertawe Bro Morgannwg University Local Health board; Professor James N'Dow, Consultant Urological Surgeon, University of Aberdeen and NHS Grampian; Dr Jon Rees, General Practitioner, Nailsea, Bristol; Dr Julian Spinks, General Practitioner, Strood, Kent; Mr Mark Speakman, Consultant Urological Surgeon, Taunton and Somerset NHS Trust; Mr William Turner, Consultant Urological Surgeon, Addenbrooke's Hospital, Cambridge; Dr Adrian Wagg, Consultant Geriatrician, UCL Hospitals Foundation NHS Trust and Camden PCT

## 2015 Update

*Clinical Guidelines Update Team Members:* Philip Alderson, Clinical Adviser; Emma Banks, Co-ordinator; Sara Buckner, Technical Analyst; Paul Crosland, Health Economist; Nicole Elliott, Associate Director; Sarah Glover, Information Scientist; Susannah Moon, Programme Manager; Rebecca Parsons, Project Manager; Charlotte Purves, Administrator; Toni Tan, Technical Adviser

*Standing Committee:* Members of Standing Committee A and the topic experts for the 2015 update are listed on the [National Institute for Health and Care Excellence \(NICE\) Web site](#) .

## Financial Disclosures/Conflicts of Interest

### 2010 Guideline

All members of the Guideline Development Group (GDG) and all members of the National Clinical Guideline Centre (NCGC) for Acute and Chronic Conditions staff were required to make formal declarations of interest at the outset, and these were updated at every subsequent meeting throughout the development process. The GDG members' declarations of interests are listed in Appendix B of the full version of the guideline (see the "Availability of Companion Documents" field).

### 2015 Update

The conflicts of interest policy (2007) was followed until September 2014, when an updated policy was published. Section 4.4 in the original guideline document lists the GDG members' declarations of interests.

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Clinical Guideline Centre for Acute and Chronic Conditions. Lower urinary tract symptoms. The management of lower urinary tract symptoms in men. London (UK): National Institute for Health and Clinical Excellence (NICE); 2010 May. 34 p. (Clinical guideline; no. 97)

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic copies: Available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) . Also available for download in ePub and eBook formats from the [NICE Web site](#) .

## Availability of Companion Documents

The following are available:

- The management of lower urinary tract symptoms in men. Full guideline. London (UK): National Institute for Health and Care Excellence;



2010 May. 355 p. (Clinical guideline; no. 97). Electronic copies: Available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) .

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- The management of lower urinary tract symptoms in men. Costing report. London (UK): National Institute for Health and Care Excellence; 2010 May. 29 p. (Clinical guideline; no. 97). Electronic copies: Available from the [NICE Web site](#) .
- The management of lower urinary tract symptoms in men. Costing template. London (UK): National Institute for Health and Care Excellence; 2010 May. (Clinical guideline; no. 97). Electronic copies: Available from the [NICE Web site](#) .
- Lower urinary tract symptoms in men: assessment and management. Implementation briefing for general practitioners (GPs). London (UK): National Institute for Health and Care Excellence; 2015 Sep. 6 p. (Clinical guideline; no. 97). Electronic copies: Available from the [NICE Web site](#) .
- Lower urinary tract symptoms in men: assessment and management. Implementation briefing for pharmacists. London (UK): National Institute for Health and Care Excellence; 2015 Sep. 6 p. (Clinical guideline; no. 97). Electronic copies: Available from the [NICE Web site](#) .
- Lower urinary tract symptoms in men: assessment and management. Slide set. London (UK): National Institute for Health and Care Excellence; 2015 Sep. (Clinical guideline; no. 97). Electronic copies: Available from the [NICE Web site](#) .
- The guidelines manual 2012. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. Electronic copies: Available from the [NICE Web site](#) .

## Patient Resources

The following is available:

- Lower urinary tract symptoms in men: assessment and management. Information for the public. National Institute for Health and Care Excellence (NICE); 2010 May. 12 p. (Clinical guideline; no. 97). Electronic copies: Available from the [NICE Web site](#) . Also available in ePub and eBook formats from the [NICE Web site](#) . Also available in Welsh from the [NICE Web site](#) .

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